



141-239

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Dixit et al.

Serial No.: 10/726,024

Group Art Unit: --

Filed: December 2, 2003

Examiner: --

For: ORAL CONTROLLED RELEASE ORAL DOSAGE FORM

New York, NY 10036
February 27, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

Document
Designation

AA
U.S.P. 4,519,801

Relevance

Relates to an osmotic device with a wall comprising a cellulose
ether and a permeability enhancer.

AB
U.S.P. 4,612,008

Relates to an osmotic device with dual thermodynamic activity.

AC
U.S.P. 4,783,337

Relates to an osmotic system comprising a plurality of
members for dispensing drug.

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope
addressed to:

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
on February 27, 2004

Nicholas P. Chiara, Reg. No. 52,737

<u>Document Designation</u>	<u>Relevance</u>
AD U.S.P. 4,874,613	Relates to a taste concealing pharmaceutical dosage unit.
AE U.S.P. 4,894,240	Relates to a controlled absorption diltiazem formulation for once-daily administration.
AF U.S.P. 4,952,402	Relates to a controlled release powder and process for its preparation.
AG U.S.P. 5,023,088	Relates to a multi-unit delivery system.
AH U.S.P. 5,082,668	Relates to a controlled release system with a constant pushing source.
AI U.S.P. 5,654,005	Relates to a controlled release formulation having a preformed passageway.
AJ U.S.P. 5,773,478	Relates to a composition comprising methylphenidate and another drug.
AK U.S.P. 5,837,284	Relates to a dosage form which delivers multiple doses of medications.
AL U.S.P. 5,874,090	Relates to a sustained-release formulation of methylphenidate.
AM U.S.P. 5,908,850	Relates to a method of treating attention deficit disorders with d-threo methylphenidate.
AN U.S.P. 5,914,129	Relates to an analgesic composition for treatment of migraine headaches.
AO U.S.P. 6,034,101	Relates to a dosage form and method for administering drug.
AP U.S.P. 6,228,398	Relates to a multiparticulate modified release composition.
AQ U.S.P. 6,322,819	Relates to an oral pulsed drug delivery system.
AR U.S.P. 6,340,476	Relates to a pharmaceutical dosage form for pulsatile delivery of methylphenidate.
AS U.S.P. 6,344,215	Relates to methylphenidate modified release formulations.

<u>Document Designation</u>	<u>Relevance</u>
AT U.S.P. 6,355,656	Relates to phenidate drug formulations having diminished abuse potential.
AU U.S.P. 6,368,626	Relates to device for controlled delivery of active agents.
AV U.S.P. 6,372,254	Relates to a press coated, pulsatile drug delivery system suitable for oral administration.
AW U.S.P. 6,417,184	Relates to a triple drug therapy for the treatment and prevention of acute or chronic pain.
AX U.S.P. 6,419,952	Relates to the conversion of liquid filled gelatin capsules into controlled release.
AY U.S.P. 6,419,960	Relates to a controlled release formulation having rapid onset and rapid decline of effective plasma drug concentrations.
AZ U.S.P. 6,495,154	Relates to an on demand administration of clomipramine and salts thereof to treat premature ejaculation.
BA U.S.P. 6,500,459	Relates to controlled onset and sustained release dosage forms and the preparation thereof.
BB U.S.P. 6,503,950	Relates to a triple drug therapy for the treatment of narcotic and alcohol withdrawal symptoms.
BC U.S.P. 6,531,489	Relates to a process for preparing a single isomer of methylphenidate.
BD U.S.P. 6,555,127	Relates to a multi-spike release formulation for oral delivery.
BE U.S.P. 6,555,136	Relates to a pharmaceutical dosage form for pulsatile delivery of methylphenidate.
BF U.S.P. 6,602,521	Relates to a multiplex drug delivery system suitable for oral administration.
BG U.S.P. 6,627,223	Relates to a timed pulsatile drug delivery system.
BH U.S.P. 6,635,284	Relates to a dosage form for delivery of multiple doses of medications.
BI U.S.P. 6,638,533	Relates to a pulse dosage formulation of methylphenidate and method to prepare same.

<u>Document Designation</u>	<u>Relevance</u>
BJ U.S.P. 6,673,367	Relates to a controlled/modified release oral methylphenidate formulation.
BK U.S.P. 6,692,767	Relates to a solid solution beadlet.
CA WO 98/06380	Relates to a dosage form for providing ascending dose of drug.
CB WO 98/14168	Relates to a dosage form and a method for administering a drug.
CC WO 98/23263	Relates to an ascending-dose dosage form.
CD WO 99/03471	Relates to a dosage form for improved delivery of multiple doses of medications.
CE WO 99/62496	Relates to methods and devices for providing prolonged drug therapy.
CF WO 00/35450	Relates to a controlled/modified release oral methylphenidate formulation.
CG EP 0 320 097	Relates to a controlled release diltiazem formulation.

In accordance with current Patent and Trademark Office practice no copies of the above listed United States Patents are filed herewith. Full text copies of all non-United States Patent references are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

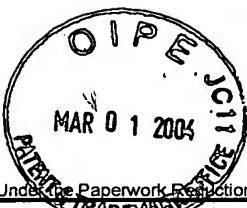
Pursuant to 37 C.F.R. §1.97 it is believed that no fee is required for consideration of this Information Disclosure Statement. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



Nicholas P. Chiara
Reg. No. 52,737

MAILING ADDRESS:
HEDMAN & COSTIGAN, P.C.
1185 Avenue of the Americas
New York, NY 10036
(212) 302-8989



PTO/SB/08A (08-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/726,024
Filing Date	December 2, 2003
First Named Inventor	Manesh Dixit
Art Unit	
Examiner Name	
Attorney Docket Number	141-239

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US- 4,519,801	05-28-1985	Edgren	
	AB	US- 4,612,008	09-16-1986	Wong et al.	
	AC	US- 4,783,337	11-08-1988	Wong et al.	
	AD	US- 4,874,613	10-17-1989	Hsiao	
	AE	US- 4,894,240	01-16-1990	Geoghegan et al.	
	AF	US- 4,952,402	08-28-1990	Sparks et al.	
	AG	US- 5,023,088	06-11-1991	Wong et al.	
	AH	US- 5,082,668	01-21-1992	Wong et al.	
	AI	US- 5,654,005	08-05-1997	Chen et al.	
	AJ	US- 5,773,478	06-30-1998	Richards et al.	
	AK	US- 5,837,284	11-17-1998	Mehta et al.	
	AL	US- 5,874,090	02-23-1999	Baker et al.	
	AM	US- 5,908,850	06-01-1999	Zeitlin et al.	
	AN	US- 5,914,129	06-22-1999	Mauskop	
	AO	US- 6,034,101	03-07-2000	Gupta et al.	
	AP	US- 6,228,398	05-08-2001	Devane et al.	
	AQ	US- 6,322,819	11-27-2001	Burnside et al.	
	AR	US- 6,340,476	01-22-2002	Midha et al.	
	AS	US- 6,344,215	02-05-2002	Bettman et al.	

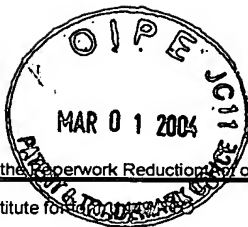
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	CA	WO 98/06380	02-19-1998	Shivanand et al.		
	CB	WO 98/14168	04-09-1998	Gupta et al.		
	CC	WO 98/23263	06-04-1998	Hamel et al.		
	CD	WO 99/03471	01-28-1999	Mehta et al.		
	CE	WO 99/62496	12-09-1999	Ayer et al.		
	CF	WO 00/35450	06-22-2000	Goldenheim et al.		

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 2**Complete if Known**

Application Number	10/726,024
Filing Date	December 2, 2003
First Named Inventor	Manesh Dixit
Art Unit	
Examiner Name	
Attorney Docket Number	141-239

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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	AT	US- 6,355,656	03-12-2002	Zeitlin et al.	
	AU	US- 6,368,626	04-09-2002	Bhatt et al.	
	AV	US- 6,372,254	04-16-2002	Ting et al.	
	AW	US- 6,417,184	07-09-2002	Ockert	
	AX	US- 6,419,952	07-16-2002	Wong et al.	
	AY	US- 6,419,960	07-16-2002	Krishnamurthy et al.	
	AZ	US- 6,495,154	12-17-2002	Tam et al.	
	BA	US- 6,500,459	12-31-2002	Chhabra et al.	
	BB	US- 6,503,950	01-07-2003	Ockert	
	BC	US- 6,531,489	03-11-2003	Harris et al.	
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	BJ	US- 6,673,367	01-06-2004	Goldenheim et al.	
	BK	US- 6,692,767	02-17-2004	Burnside et al.	
		US-			

FOREIGN PATENT DOCUMENTS

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		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
	CG	EP 0 320 097 A1	06-14-1989	Geoghegan et al		

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Considered

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